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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,503	05/31/2001	Lawrence R. Green	033599-019	2081

21839 7590 09/29/2004

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,503	GREEN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/10/2004 revival*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/31/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment to the claims filed on 1/29/2004 does not comply with the requirements of 37 CFR 1.121(c) because it amends previously cancelled claims 1-30, and does not include a listing of claims 31-47 which were previously added. In the interest of compact prosecution, after consulting with the applicant's representative, claims 1-30 have been treated as cancelled, not amended, and claims 31-47 have been examined. Also, the amendment is not fully responsive to the Sequence rule requirements, because it does not add SEQ ID numbers in claims 31-47. Applicant is required to add SEQ IDs to the claims in response to this office action.

Claim Rejections - 35 USC § 112

Claims 31-40, 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31, on first reading, appears adequately clear. However, claim 40 recites "The method of claim 31, wherein said peptide...is administered as a pharmaceutical composition." This confuses the intended meaning and scope of claim 31 – how can the body-treating method of claim 31 be practiced without using the peptide in a composition appropriate for body treatment? What kind of non-pharmaceutical compositions are contemplated for use in claim 31? Since claim 40 confuses the intended meaning of claim 31, claims 31 and dependent claims 32-40, 45-47 are rejected as indefinite.

Claims 31-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for augmenting vaccination in a fish using HM897 peptide (Thr-Ala-Glu-Glu-Lys), does not reasonably provide enablement for the full scope of augmenting vaccination in any host using any 2-9 residue peptide comprising Glu-Lys or Gln-Lys. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims are drawn to a method of augmenting vaccination, which the examiner has interpreted as a method of improving response to vaccination. There are two issues here, the scope of host animal vaccinated and the scope of peptide used as an adjuvant. The specification provides one working example, where the protective immune response to a fish pathogen is improved using the pentapeptide HM897. Warr (Developments in Biological Standardization 90:15-21, 1997) is cited as evidence that the immune response of fish is not representative of the immune response of mammals; see for example page 16, which states in part: "fish (above the level of agnatha) possess all the basic mechanisms and, in some form, the molecules of higher vertebrate immunity...This is not to imply that fishes have immune responses like mammals: this is clearly not the case. " Therefore, one skilled in the vaccine art would not unquestioningly accept that results obtained in fish would be predictive of vaccination results in other hosts such as mammals.

In regard to the scope of peptides used, the review by Werner (Immunology Letters 16:363-70, 1987) indicates that immunostimulating peptides vary widely in

structure and biological activity affecting the various parts of the immune system. Werner also points out that the peptides differing in structure by a single residue (TKPR and TKP) have opposite biological effects. Therefore, in this art, one cannot a priori predict the biological activity of any particular peptide based upon a limited similarity in structure to another peptide.

Considering the unpredictability of the art, the limited teachings in the specification, the broad scope of the claims, and the limited scope of the working examples, it is concluded that undue experimentation would be required to practice the full scope of the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31, 34, 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyeki et al US 5041535. Nyeki teaches two immunostimulating peptides of less than 9 amino acids comprising DK residues which are able to improve antibody production in immunosuppressed mice when administered after presentation of an immunizing antigen. See Table 3, lines 2 and 10. This differs from the invention in that Nyeki used sheep erythrocytes as a test antigen, and the claims require a vaccine. Nyeki also fails to teach the concentration of the peptide in the composition administered, or to teach details such as the buffer used in the carrier, and teaches only intraperitoneal administration. However, considering the improved antibody response to a test antigen, it would have been obvious to use the same peptides to improve the antibody response to a vaccine, and it would have been a matter of routine optimization to determine effective concentrations, carriers, and routes of administration. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Allowable Subject Matter

Claims directed to a method for augmenting vaccination in a fish comprising administering Thr-Ala-Glu-Glu-Lys and a vaccine, would be allowable.

Information Disclosure Statement

In the Information Disclosure Statement filed 5/31/2001, documents BM, BP, and CF could not be readily located in a parent application, and the relevance could not be assessed by the information on the form PTOL-1449. Could applicant provide a copy of these documents?

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/24/04

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600